**UNITED STATES PATENT AND TRADEMARK OFFICE**

_____

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

_____

**REGENERON PHARMACEUTICALS, INC.,**
Petitioner

v.

**NOVARTIS PHARMA AG,**
**NOVARTIS TECHNOLOGY LLC,**
**NOVARTIS PHARMACEUTICALS CORPORATION,**
Patent Owner

_____

**Case IPR2021-00816**
Patent 9,220,631

_____

# DECLARATION OF ANDREW F. CALMAN, M.D., PH.D., IN SUPPORT OF PATENT OWNER RESPONSE

## TABLE OF CONTENTS

## I. INTRODUCTION

1. I, Andrew F. Calman, M.D., Ph.D., have been retained by Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp. (collectively, "Patent Owner" or "Novartis") as an independent expert witness in the above-captioned *inter partes* review ("IPR"), in which Petitioner Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron") has requested that the U.S. Patent and Trademark Office cancel as unpatentable all claims of U.S. Patent No. 9,220,631 ("the '631 patent"). This declaration sets forth my opinions based on the materials I have considered and my knowledge, education, skills, training, and experience.

2. I provide this declaration to provide medical and ophthalmological context for the '631 patent and the claims contained therein, including a description of age-related macular degeneration and its treatments, injection of drugs directed against vascular endothelial growth factor (VEGF), and the factors and considerations that a clinician would have found important as of the priority date of the '631 patent with regard to drug injection devices, particularly pre-filled syringes (PFS).

## II. QUALIFICATIONS AND COMPENSATION

3. I graduated in 1982 from Yale University, having earned both my B.S. (*summa cum laude*, with Distinction in the Major) and my M.S. in Molecular

Biophysics and Biochemistry in four years. I then spent seven years at the University of California, San Francisco ("UCSF"), earning an M.D. and a Ph.D. in Microbiology and Immunology. While in medical and graduate school, I earned the Dean's Prize for Student Research, the Chancellor's Fellowship, and received the E.E. Osgood Award from the American Federation for Clinical Research, awarded for the best student research in the Western United States. My published research (including two papers in *Nature* and two in the *Proceedings of the National Academy of Sciences*) included identification of a human T-cell antigen receptor gene, an *in vitro* model of immune deficiency, and mechanisms of HIV gene activation.

4. I went on to pursue a year of medical internship, during which time I oversaw a UCSF laboratory team responsible for isolating a human galactokinase gene, followed by ophthalmology residency training at UCSF. During the eleven years that I spent working in research laboratories, from undergraduate to internship, I was exposed to a variety of methods in biochemistry, microbiology, immunology, and molecular genetics, including gene splicing, manipulation of DNA, RNA, and proteins, production and use of antibodies including monoclonal antibodies, growth of bacterial and viral cultures, and various types of sterilization.

5. Since completing my ophthalmology residency training in 1993, I have served on the UCSF clinical faculty, currently as Associate Clinical Professor

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.